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FILING DATE: *June 18, 2002*
RELATED PCT APPLICATION NUMBER: *PCT/US03/19344*

By Authority of the
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ATTORNEY DOCKET NO. 21087.0022U1

06/18/02 JC849 U.S. PTO

J1002 U.S. PTO 60/389850

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a **PROVISIONAL APPLICATION FOR PATENT** under 37 C.F.R. § 1.53(c).

	Docket Number 21087.0022U1		+	

INVENTOR(s)/APPLICANT(s)

LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (City and Either State or Foreign Country)
Shields	Richard		Iowa City, Iowa

TITLE OF INVENTION (280 characters max)

"THERAPUETIC EXERCISE SYSTEM FOR A PARALYZED HUMAN NEUROMUSCULOSKELETALSYSTEM"

CORRESPONDENCE ADDRESS

Gregory J. Kirsch, Esquire
NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta

STATE	Georgia	ZIP CODE	30303-1811	COUNTRY	U.S.A.

ENCLOSED APPLICATION PARTS (*Check All That Apply*)

☒ Provisional Application Cover Sheet	*Number of pages*	[1]
☒ Specification	*Number of pages*	[7]
☐ Claims	*Number of pages*	[ ]
☐ Abstract	*Number of pages*	[ ]
☐ Drawing(s)	*Number of Sheets*	[ ]
☐ Small Entity		
☐ Power of Attorney		
☐ Assignment		
☐ Other (Specify):		

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METHOD PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (*Check One*)			
☒	A credit card payment form PTO-2038 is enclosed to cover the filing fees.	**FILING FEE AMOUNT**	$80.00
☐	The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number:		
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes. The name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE ______________ **Date** 06/18/02

TYPED or PRINTED NAME: **Gregory J. Kirsch** **REGISTRATION NO.** **35,572**
(If Appropriate)

NEEDLE & ROSENBERG, P.C.
The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Invoice No. EL924206689US in an envelope addressed to: BOX PROVISIONAL APPLICATION, Commissioner for Patents, Washington, D.C. 20231, on this 18 day of June, 2002.

David Thorpe

6-18-02
DATE

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Express Mail No.: EL924206689US
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PATENT

PROVISIONAL APPLICATION FOR UNITED STATES LETTERS PATENT

TO ALL WHOM IT MAY CONCERN:

Be it known that I, Richard Shields, a resident of the United States, have invented new and useful improvements in

"THERAPUETIC EXERCISE SYSTEM FOR A PARALYZED HUMAN NEUROMUSCULOSKELETAL SYSTEM"

For which the following is a specification.

THERAPUETIC EXERCISE SYSTEM FOR A PARALYZED HUMAN NEUROMUSCULOSKELETAL SYSTEM

Invention Description

The invention described herein is thought to be a new and novel paradigm for the therapeutic exercise of the human neuromusculoskeletal system from muscle paralysis or muscle weakened by neurological compromise. The paradigm is not limited to any particular joint, muscle, or type of contraction or any combination thereof, and is applicable to able-bodied individuals. However, the development has most recently focused on enabling individuals with complete paralysis the opportunity to actively stand under their own muscle power. The benefits of exercise can hardly be overstated. Indeed, individuals with paralysis suffer from several secondary medical complications because of the lack of a method to actively exercise the paralyzed extremities. These complications easily account for several millions of dollars in health care costs each year and without question impair the health related quality of life of these individuals. A safe method to exert physiological strains to the paralyzed lower extremities does not presently exist.

This invention can use open loop or closed loop control to modulate the electrical activation of human paralyzed muscle to induce functional standing and optimal lower extremity loading. Most importantly, the system is safe by providing passive standing in the event that the muscle or electrical stimulation system is unable to maintain the forces across the knee during the active contraction. The ability to actively stand under one's own muscle forces has several positive effects. First, just by having individuals with paralysis out of their wheelchairs eliminates the loads placed on the buttocks, the primary site for pressure sores. Second, bone loss (osteoporosis) after paralysis is extensive causing the long bones of the leg to become brittle and fracture with little or no trauma. Studies from space flight indicate that not only is weight bearing important to maintain bone, but the forces applied through muscle contractions are essential to sustain the health of the skeletal system. Bone

loss after paralysis causes increased blood calcium, which ultimately must be filtered by the kidneys. Renal and bladder stones are partly attributable to high blood calcium levels. Third, the muscle's strength and endurance are increased from the exercise. Fourth, the psychological well being of the individual that exercises daily through standing may be enhanced.

This concept is unique for several reasons. First, by having the ability to feedback information like force, velocity, acceleration, etc. the optimal method of activating paralyzed muscle can be determined. Indeed, the greater the muscle forces the greater the loads applied to the skeletal system. Also, the longer the muscles can generate force, the cumulative sum of the loading increases to the bones. Second, low strains exerted to the limbs are insufficient to prevent osteoporosis and represent an important limitation of present exercise technology for individuals with paralysis. That is, present technology induces cycling or assisted walking through electrically driven muscle contractions, but the forces placed on the lower extremity bones are marginal and not conducive to maintaining bone integrity. The present invention provides fixed or variable resistance adjustments that assure higher loads are placed on the skeletal system. Indeed, loads through the extremities are optimized to enhance maintaining the musculoskeletal integrity following paralysis. Third, the biomechanical design of the present invention optimizes axial loads through the extremities, which are the loads most conducive to preventing bone loss. Previous technologies exert tangential forces on the paralyzed extremities, which are less conducive to bone growth and increases the risk of a fracture. Fourth, the issues of safety and cost have been important limitations to previous technology. Systems for ambulation have been primarily restricted to clinical use because if the system fails the individual is at risk for a fall. While cycling systems are safer, they do not exert important axial loads, enable the individual to get out of a chair, and are extremely expensive so that widespread use is not feasible. The present invention integrates passive standing with active standing against a variable resistance. Hence, the whole spectrum of exercise from passive standing to active standing to standing against resistance can be employed. If at anytime the active standing component fails, the

individual assumes the passive standing condition. Lastly, this technology is transferred to the everyday user by incorporating many of these key developments into a standing wheelchair. The total standing wheelchair system monitors force, chair angle, and dose of standing. From these measures, a biomechanical model can indicate the % of body weight that has been exerted through the extremities. From this, the appropriate dose of load necessary to prevent bone loss can be provided to the client.

Description of the Invention

The conceived invention could take many different forms depending on the specific musculoskeletal complex being targeted for exercise. Notwithstanding the various forms that this invention may reasonably take and whether or not a degree of volitional motor control is available to assist or inhibit the desired muscle exercise, the primary application of the invention would embody the following elements:

1. A means of supporting, positioning, and protecting the exercising subject as necessary or desirable such as to allow the target musculoskeletal complex to be targeted. For example, if the target complex is extension and flexion of the knee during stance, the design would utilize a commercial structure that would support the passive upright standing condition so that the active component could produce the greatest therapeutic benefit.

2. A means for producing and applying electrical muscle stimulation to the target musculature to produce graded muscle contraction as appropriate for the exercise mode and therapeutic goal.

3. A means of applying controlled mechanical resistance such as to resist the action of a muscle or muscles thereby controlling the motion of the target musculoskeletal complex.

4. A means of producing integrated control of both the stimulator and the resistance device needed to control the movement of the target musculoskeletal complex in the manner desired to produce the therapeutic exercise goal.

5. A means of transferring this technology from the laboratory to the home by adapting the system to a commercially available standing wheelchair. This includes the utilizing a device that has the ability to monitor and store online the chair angle, muscle forces, duration of standing and subsequently feed this information back to the client so that optimal stimulation and/or optimal daily skeletal bone loading may occur.

The use of electrical stimulation to invoke muscle contraction as a therapeutic modality and as a means of producing beneficial movement or assisted locomotion of paralyzed individuals has been documented. The control of these stimulators can best be described as gross, in that no attempt is made to modify the stimulation parameters based on a motor control strategy in standing.

An angle and force recording device is utilized to measure the tilt angle of the fore mentioned standing wheelchair by using an integrated-circuit accelerometer. The integrated circuit accelerometer provides an analog voltage proportional to the static g-force in the plane of the angle and force recording device circuit board. The angle and force recording device circuitry may embody a microcontroller IC, EEPROM (non-volatile) memory IC's, a real-time clock IC, the accelerometer IC, amplifiers for the accelerometer and external force transducer and power supplies. The microcontroller contains internal D/A converters for digitizing the tilt and force signals, and internal ROM code to implement the logging programs. In use, the tilt angle and force data are sampled and periodically recorded to memory with time and date stamp, according to programmed criteria. A parallel port interface allows the recorded data to be read by a host computer, and the logger to be controlled or programmed. An external LCD display on the parallel port provides the user

with appropriate feedback data and instructions according to the program. The recording device is mounted to the wheelchair such that the accelerometer tilt reflects the standing angle, and the chair's standing-motor batteries power it. A governing biomechanical equation use the angle and force data to mathematically determine the shear and compressive loads on the bone, and provides this information to the wheelchair user. In addition, the integral of the muscle force-time curve provides feedback to the client about the muscle work completed with each bout of exercise. The electrical stimulator is battery powered, pre-programmable, and the pattern of stimulation recorded to memory with time and date stamp, according to the programmed criteria. A parallel port interface allows the recorded electrical stimulation data to be read by a host computer.

The invention improves on present technology by integrating the elements described above with intelligent motor control algorithms. In this context, intelligent motor control refers to the ability to interactively control both the stimulation parameters and the resistance device in such a way that the targeted movement or type of muscle contraction may occur in a manner deemed most beneficial to the exerciser. Conceptually, this invention can be thought of as a means of placing a targeted musculoskeletal complex into a fixture whose purpose is to exercise the complex in a prescribed manner under controlled conditions. The novelty of the invention is the introduction of an external motor control intelligence which is capable of interacting with the exerciser's own volitional motor control tactics, or where higher level motor control is compromised or absent, to become the primary center for motor control.

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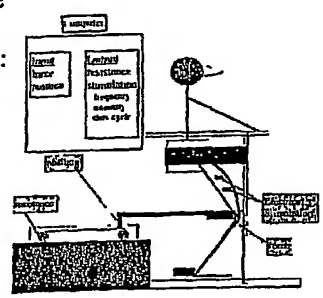
Novel Paradigm for Therapeutic Exercise of the Human Neuromusculoskeletal System.

a. Emphasis on Paralyzed Lower Extremities in Stance.

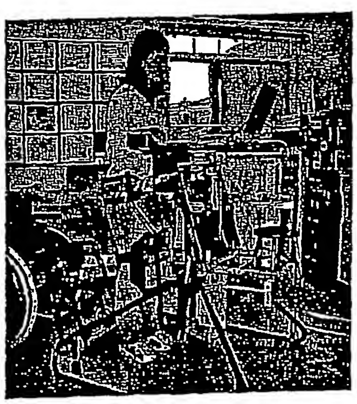
This system shows the principles of the active standing system in the laboratory.

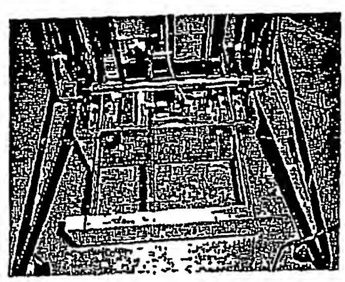
Measurement Components include:

1. Force
2. Position/velocity/acceleration
3. Braking mechanism
4. Electrical stimulation
5. All components are interfaced through software control.



*note: see next figure for picture of actual system





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B. Similar technology transferred to everyday stand-up wheelchair.

Stand up wheelchairs already exist. We have developed the following:

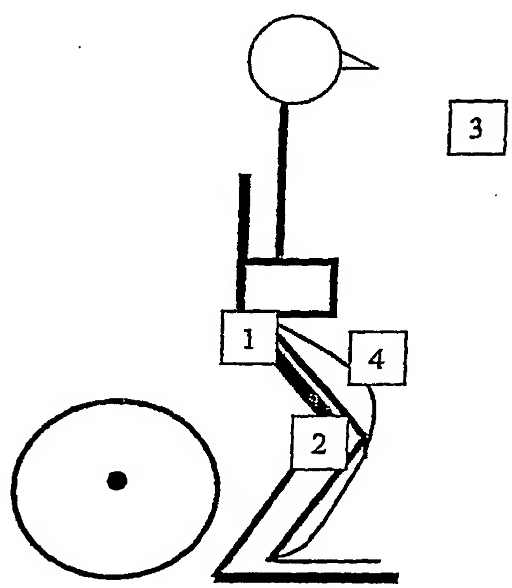
1.Tilt sensor which stores the angle, total time at the angle, and software to download the information stored for up to 3 months.

2.Force system which records the force and analyzes the axial and tangential loads on the skeletal system. This information can be fed back to the client via a digitial display. (see 3)

3.Digital display: provides feedback to client about the amount of load placed through extremities on a given day.

4.Battery powered stimulator drives the quadriceps muscle.

5.Software which interfaces angle, force, etc, data to computer for download and management.



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☑ ***Scanned copy is best available.*** Picture on page six of Specification is very dark